

REMARKS

Upon entry of this amendment, claims 28-39 will be pending. Applicants respectfully disagree with the rejections set forth in the Office Action dated July 1, 2004, and maintain that claims 16-27 are patentable. However, for clarity, Applicants hereby cancel claims 16-27, and submit new claims 28-39. The new claims are fully supported by the specification at, for example, paragraphs [0016] and [0017], and the original claims.

Claims 16-27 stand rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by U.S. Patent No. 5,877,309 (hereinafter the “309 patent”). The cancellation of claims 16-27 renders the rejection moot.

The new claims are not anticipated by the 309 patent. The new claims clarify that that the method of enhancing the absorption of a drug entails activating the intestinal tissue with a penetrating enhancer prior to allowing a drug to interact with said intestinal tissue (e.g., claims 28 and 30). The prior activation may be achieved through administering two separate population of carrier particles (e.g., a first population of carrier particles and a second population of carrier particles). As explained by the specification at paragraph [0017]:

Upon dissolution in the intestine, the penetration enhancers [of the second population of carrier particles] are released and move down the intestine while acting on the mucosal membrane. Concurrently, the drug-bioadhesive component [of the first population of carrier particles] adheres to the mucosal membrane and into the luminal solution from where it can also be absorbed.

Further, the first population and second population are separate in that the first population may be prepared as a tablet or a multiparticulate formulation, and the second population may be prepared as a separate tablet, multiparticulate, emulsion, microemulsion or self-emulsifying system.

Although the 309 patent reports a mixture comprising a polyacrylate (a bioadhesive) (col. 23, ln. 39) and a capric acid (a penetration enhancer) (col. 22, ln. 17), the 309 patent fails to teach that the polyacrylate is part of “a first population of carrier particles comprising a drug-bioadhesive component”, and that the capric acid is part of separate/different “second population of carrier particles”. For example, the 309 patent does not disclose that the first population may be prepared as a tablet or a multiparticulate formulation, and the second population may be prepared as a separate tablet, multiparticulate, emulsion, microemulsion or self-emulsifying system. Thus, the 309 patent does not teach all the elements of claims 28-39 to anticipate.

Claims 16, 21 and 25 stand rejected under 35 U.S.C. § 103 (a) for allegedly being obvious over the 309 patent in view of U.S. Patent No. 5,514,788 (hereinafter the “788 patent”). The cancellation of claims 13, 21 and 25 renders the rejection moot. Further, the new claims are not obvious over the 309 patent in view of the 788 patent, because the 788 patent does not cure the deficiencies of the 309 patent.

In view of the foregoing, Applicants submit that the pending claims are in condition for allowance, and an early Office Action to that effect is earnestly solicited.

Respectfully submitted,



Quan L. Nguyen
Registration No. 46,957

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COZEN O'CONNOR
1900 Market Street
Philadelphia, PA 19103
(215) 665-2158 (phone)
(215) 701-2057 (fax)

Enclosures:

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